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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,798	03/24/2000	Miles William Carroll	078883/0120	2448

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/533,798	CARROLL ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-16,18-34 and 41-52* is/are pending in the application.

4a) Of the above claim(s) *1-4,6,8,13,15,18-34 and 41-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12, 14, 16, 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Please note the application has been transferred to a new examiner, as Examiner Scheiner is no longer with Office. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Salimi.

Election/Restrictions

The previously mailed written restriction mailed 8/22/2003 is vacated.

Response to Amendment

This is a response to the amendments filed 9/26/2003, and 6/19/2003. Claims 46-52 have been added. Claims 1-4, 6, 8-16, 18-34, and 41-52 are pending. Claims 1-4, 6, 8, 13, 15, 18-34, 41-45 were withdrawn from consideration based on election filed January 02, 2003. Claims 9-12, 14, 16, and 46-52 are considered.

Election/Restrictions

Newly submitted claims 46-51 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants received an office action on 3/19/2003 whereby Applicants made an election of Group IIII (consisting of Claims 9-12, 14, and 16) with traverse. Examiner of record did not find Applicants' argument convincing and maintained the requirement and only examined the elected claims, and mailed an Office Action to the Applicants. Subsequently, Applicants deciding not to petition the finality of the requirement and assented to the finality of requirement, but kept the non-elected claims pending.

In the response to the Office Action, dated 6/19/2003 Applicants added Claims 46-52 and required the examination of new claims in addition to the already examined claims.

The claims 46-52 are, however, directed to a new invention that is different than the claimed invention that was previously examined on the merit. The newly submitted claims are directed to "modified 5T4" antigens, which comprise eptitopes of unmodified 5T4 antigens. The inventions are mutually exclusive and patentably distinct products each are structurally and functionally different products, which are made by different methods and have different uses and delineate different results, and have different effect on interaction, antigenicity and immune response. The newly added claims comprises all types of deletion, and mutations in multiple and various regions wherein each mutation is different and presumably has different effect on interaction, antigenicity. The effects of the mutations, or deletions, are unpredictable and the said modifications at one location do not teach or suggests effects at a different location. Moreover, the activity of each variant peptide is different. Their structures and functionalities are different. Still further, newly added claims are broader in nature than the elected claims, for instance the amended claim 9 is limited to "non-human 5T4 antigen" but the 5T4 antigen of claim 46 is directed to any and all 5T4 antigens. Clearly, the scope of claim 46 is larger than claim 9. Applicant has already received an action of the merit and the newly added claims are distinct. The examination of all groups would require different searches in the U.S. Patent Shoes and scientific literature and would require the consideration of different patentability issues.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 46-51 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Hence, Only Claims **9-12, 14, 16, and 52** will be considered.

Claim Rejections - 35 USC § 112

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 3/19/2003. Applicants argue that the newly amended claim is directed to "modified 5T4 antigen comprising an HLA CTL peptide epitope and not a peptide per se. In addition, Applicants refer the Office to page 6, lines 1-7 of the disclosure for the claimed invention. Page 6 lines 1-7, recite: "Modified peptides are advantageously HLA CTL epitopes of 5T4. Modification of such epitopes may be performed based on predictions for more efficient CTL induction derived using the program "Peptide Binding Predictions" devised by K. Parker (NIH) which may be found at http://www-bimas.dcrt.nih.gov/cgi-bin/molbio/ken parker comboform (see also Parker, K. C et al. 1994.J.Immunol. 152:163)." Still further, Applicants refer to Example 10 as providing a list of 23 polypeptides comprising HLA CTL epitopes. Applicants go one to assert that the program identified two amino acid changes increased by 10 fold a 9mer's half time of dissociation from HLA found. Applicants conclude that disclosure provided adequate disclosure. Applicant's argument as part of amendment 6/19/2003 has been considered fully, but they are not persuasive. Applicants disclosure on page 6, lines 1-7, is far from having adequate disclosure. The disclosure asks others to fully enable the claimed invention while they are benefiting from patent protection. Applicants' own disclosure must be adequately disclose the invention. Applicants assertion are unsubstantiated. There is nothing in the disclosure that shows any CTL response was observed. All the results in the disclosure

show antibody response. Applicants cannot rely on others to enable their claimed invention. The disclosure does not set forth any CTL epitopes. Chopping a well characterized protein into various pieces and then asserting that the proteins would include a CTL response is not an adequate disclosure. Additionally, none of the laundry list of peptides that are in Tables 4 or 5 have been demonstrated to induce CTL response. Moreover, applicants are inducing or claiming to induce CTL against a self antigen, after all the claimed antigen is a tumor antigen which is self antigen. This is not a routine experimentation of injecting a foreign 9 or 10mer polypeptide and hoping MHC I would get involve and present the antigen and CTL would be induced. In an unpredictable filed, such as this, the disclosure must adequately teach the invention. Still further, with regard to "modified protein" and increased dissociation, Applicants' claimed invention is not an in vitro measure of dissociation. The claimed invention is directed to induction of anti-tumor immunotherapeutic response wherein 5T4 antigen comprises HLA CTL peptide epitope of 5T4 antigen. No such response has been taught, there is nothing in the specification that shows CTL response against a self 5T4 antigen was observed. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 102

Claims 9-12, 16, and 52 are is rejected under 35 U.S.C. 102, as being anticipated by Stern et al (U.S Patent No. 5,869,053) for reasons of record advanced in the previous Office Action mailed 3/19/2003. Applicants argue that the patent neither teaches nor suggests that: (a) non-human 5T4 antigens can be used in vaccine or (b) 5T4 antigens induce an anti-tumor immunotherapeutic response. Applicants assert that ,053 patent is limited to human 5T4 glycoprotein. Applicant's argument as part of amendment 6/19/2003 has been considered fully, but they are not persuasive. Applicants are reminded that if the prior art structure is capable of

performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, Applicants are directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting, it simply has not invented anything new." This is the case here, while the Applicants may have "Observed" something interesting they have not invented anything new. The product is the same since the claim does not distinguish it form the teaching of Stern et al, because frankly it cannot. The state of art indicates that the glycoprotein of Stern et al is highly identical to the Non-Human. The product claimed has the same structure as the now claimed product. Moreover the claims of Stern patent are not directed to a protein having a specific characteristics, they are not directed to a human or non-human. As a pioneering invention claim of ,053 is subject to broad interpretation. Additionally, claims 12, and 16 are directed to antibody response just the same as teaching of Stern et al. The rejection is maintained.

New Grounds of Rejection:

Claim Rejections - 35 USC § 112

Claims 14, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The claims are rejected to limitations of "modified", this is a relative term, and is subject to varied interpretation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. In the instant disclosure, the applicants have only disclosed the sequences identified as SEQ ID NO: 3 as a canine 5T4. No other sequences of non-human 5T4 were disclosed. The specification does not set forth the metes and bounds of that "non-human 5T4 antigen", and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed genus. Therefore, a written description of the other claimed sequences of 5T4 antigens should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the

invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 19 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 10, 11, 12, 16, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Stern et al (WO 89/07947).

The above cited reference taught the same product that is now being claimed by the Applicants. Applicants are reminded that the patent Office does not have facilities to conduct a head to head comparison. In addition, Applicants are reminded that if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-12, 14, 16, and 52 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Myers et al (J. of Biological Chemistry, 1994).

Myers et al taught the product that is now being claimed by the Applicants (see Figure 3). If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Alternatively, as it applies to claims 14 or 52, it would have been obvious to one of ordinary skill in the art to modify the peptides identified in Figure 3 to be utilized in induction of immune response either as an antibody response or a CTL response to treat tumors in a suitable host. The peptides are short and modification would only be limited, and Applicants in their own disclosure see page 6, lines 1-7 admit that modifying a peptide is within a purview of ordinary skill in the art. Thus, one of ordinary skill in the art being familiar with the state of the art would not have anticipated any unexpected results to modify the peptides taught by Myers et al to be used to treat cancer. Thus, the invention as a whole is prima facie obvious absent unexpected result.

No Claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi
7/11/2005